K130624
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510(k) Summary
GlobalMedia Group, LLC.
CONi™

MAY 0 7 2013

Date Prepared: January 8, 2013

Submitter's Information:

GlobalMedia Group, LLC
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Scottsdale, AZ 85260

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Trade Name, Common Name and Classification:

Trade Name: CONi®
Device Classification Regulation: 892.2050 – Picture Archiving Communication System
Product Code: LLZ – System, Image Processing, Radiological

Predicate Device:

Trade Name: ALZ Web PACS (Version 1.0)
Device Classification Regulation: 892.2050 – Picture Archiving Communication System
Product Code: LLZ – System, Image Processing, Radiological
Applicant: ALZ, Inc.
510(k) Number: K081304

Device Description:

CONi (Capture Over Network Interface) is a secure cloud-based application for viewing and archiving medical images. The CONi software system is comprised of a Picture Archiving and Communication System (CONiPACS) and an image viewer (CONiView). CONi supports imaging studies from the following DICOM modalities: Computed Tomography (CT), Magnetic Resonance (MR), X-ray (CR), Ultrasound (US), and Visible Light (External Camera (XC) and Other (OT)). Images and information can be viewed and stored via a secure Internet connection.

Studies can be shared with a specialist at another facility quickly with a study-specific passcode. This facilitates remote consultation and expedites the study transfer process in emergency situations when a patient is being transported. No physical media such as CDs are needed because collaboration occurs entirely over an internet connection. Secondary over-triage can even be avoided.

Intended Use:

CONi provides for the archiving and viewing of medical images from the following DICOM modalities: Computed Tomography (CT), Magnetic Resonance (MR), X-ray (CR), Ultrasound (US), and Visible Light (External Camera (XC) and Other (OT)). Images and information can be viewed and stored via a secure Internet connection.

CONi is not intended for use in mammography.

Technological Characteristics and Substantial Equivalence

The proposed and predicate devices provide a web-based system for the archiving and viewing of medical images. The proposed and predicate devices are to be used with general purpose computing hardware to acquire, transmit, or view the stored medical images. Equivalent with the predicate device, CONi consists of a software application that is installed in a hosted server environment that will communicate with the client's PCs via an internet connection. Communication between the CONi application and client's PCs utilizes DICOM protocols and encrypted browser communications. Both the proposed and predicate devices are hosted by HIPAA compliant facilities. File acquisition, sending functions, and image view and manipulation are included in the proposed and predicate devices.

Substantial Equivalence Table:

	GlobalMedia Group CONi	**ALZ Web PACS (Version 1)**
Device Description	CONi (Capture Over Network Interface) is a secure cloud-based application for viewing and archiving medical images. The CONi software system is comprised of a Picture Archiving and Communication System (CONiPACS) and an image viewer (CONiView). Images and information can be viewed and stored via a secure Internet connection.	The ALZ Web PACS (Version 1.0) is designed for management, viewing, and processing of DICOM images. The ALZ Web PACS consists of the ALZ Web PACS software application installed on a server and the ALZ Web PACS viewer running on client computers connecting to the server via HTTPS protocol.
Regulation Number	892.2050	892.2050
Product Code	LLZ	LLZ
Intended Use	CONi provides for the archiving and viewing of medical images from the following DICOM modalities: Computed Tomography (CT), Magnetic Resonance (MR), X-ray (CR), Ultrasound (US), and Visible Light (External Camera (XC) and Other (OT)). Images and information can be viewed and stored via a secure Internet connection. CONi is not intended for use in	The ALZ Web PACS (Version 1.0) is an imaging software system intended to be used by trained healthcare professionals. ALZ Web PACS is used with general purpose computing hardware to acquire, transmit, store, view, and process DICOM images. The device is not intended for mammography.

	GlobalMedia Group CONi	ALZ Web PACS (Version 1)
	mammography.	
Technological Characteristics (Server)	Reliable hardware platform, preconfigured and pretested	Reliable hardware platform, preconfigured and pretested
	Multiple simultaneous DICOM associations	Multiple simultaneous DICOM associations
	Multi-modality, multi-vendor functionality and compatibility	Multi-modality, multi-vendor functionality and compatibility
	RIS incorporated	RIS incorporated
	Server monitored by GlobalMed and hosting site (FireHost)	Server instance monitoring
	Shared archive	Shared archive
	Studies are marked as reviewed after a report is written	Studies are marked as read after a DICOM query (this feature is set if client requests)
Technological Characteristics (Communication)	Not a feature	DICOM query/retrieve
	DICOM Worklist Client	DICOM Print client and DICOM Worklist client
	Automatic study routing based on administrative routing rules	Auto forward of data sets
	Compiles with DICOM standards	Complies with all HL7 and DICOM, standards
	Email notification upon arrival of new study or finished report	Email notification upon arrival of new study
	Not a feature	Emailing images as JPEG
Technological Characteristics (Licensing)	Supports all modalities except mammography	Available for all DICOM modalities
	Unlimited number of web users	Unlimited number of web users
Technological Characteristics (Web)	User-friendly web interface layout	User-friendly web interface layout
	Coherent overview of studies with search and filter possibilities	Coherent overview of studies with search and filter possibilities
	Automatic browser logout	Automatic browser logout
	Unlimited number of users and concurrent users	Unlimited number of users and concurrent users
	Display of all color/grayscale images	Display of all color/grayscale images
	PDF reports	Display of structured reports
	Transfer of images via web to DICOM destinations	Transfer of images via web to DICOM destinations
	Not a Feature	File attachments to images or studies
Technological Characteristics (Import)	Not a Feature	Import of any DICOMDIR media
	Not a Feature	Directory registration of DICOM data
Technological Characteristics (Export)	Not a Feature	DICOM export function by burning the DICOM images to a CD or by using a USB
Technological Characteristics	Automatic synchronization with remote servers	Automatic synchronization with remote servers

	GlobalMedia Group CONi	ALZ Web PACS (Version 1)
(Database)	Not a Feature	Configurable overflow management (high water/low water, study date, custom settings) if setting is requested by client
Technological Characteristics (Data Access)	Admin user	Admin user
	Predefined privileges for physicians, nurses, and technicians	Privilege settings for each user/group are customizable
	User access control	User access control
Technological Characteristics (Service)	No client software updates required	Software updates/upgrades optional
Technological Characteristics (Languages)	English, Spanish, and Portuguese	English
Technological Characteristics (Web Viewer)	Available to an unlimited number of viewers and concurrent viewers	Available to an unlimited number of viewers and concurrent viewers
	Viewing of any kind of images and PDF reports	Viewing of any kind of images and structured reports
	Center/window	Center/window
	Not a feature	Comparison of multiple studies
	Stack mode/cine mode	Stack mode/cine mode
	Not a Feature	Measurements (distance, ROI, angle)
	Thumbnail preview	Thumbnail preview
	Background preload	Background preload
	Supports DICOM compressions. Server does not compress DICOM files.	JPEG DICOM compressions vary per modality
Typical User	Trained professionals, physicians, nurses, clinicians and technicians.	Healthcare professionals
Software Level of Concern	Moderate	Moderate

Summary of Non-Clinical Tests

The following quality assurance measures were applied to the development of the CONI system:

- Establishment of Requirements
- Risk Analysis (software and system)
- DICOM Standard Conformance Statement
- HIPAA Compliance Statement
- Software Unit Testing
- Software Integration Testing
- Software System Testing
- Software Hazard Testing

Safety and Effectiveness Summary

The CONi software application provides a safe and secure location for the archiving and

viewing of medical images. CONi does not diagnosis any medical condition and is intended to be used by trained individuals. The software utilizes DICOM communication protocols and has been designed and tested to meet HIPAA requirements. CONi does not control the function of any other medical device. GlobalMedia Group considers the CONi software application to be as safe and effective for use as the previous cleared predicate device.

Conclusion

The GlobalMedia Group CONi software application has similar functionality, intended use, technological characteristics, and typical users as the predicate device. As a result, the CapSure software application will fall under the same FDA classification number and product code as the predicate device. The GlobalMedia Group CONi software introduces no new issues or concerns of safety and effectiveness, and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 7, 2013

Globalmedia Group LLC
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K130624
Trade/Device Name: CONi™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 23, 2013
Received: April 24, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130624

Device Name: CONi®

Indications for Use:

CONi provides for the archiving and viewing of medical images from the following DICOM modalities: Computed Tomography (CT), Magnetic Resonance (MR), X-ray (CR), Ultrasound (US), and Single Frame Visible Light Photography (External Camera (XC) and Other (OT)). Images and information can be viewed and stored via a secure Internet connection.

CONi is not intended for use in mammography.

CONi is not intended for diagnostic use on mobile devices

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) _____ K130624_____